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Ladas & Parry
26 West 61 Street
New York, NY 10023

EXAMINER

SMALL, ANDREA D SOUZA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/032,392

Applicant(s)

NATESAN ET AL.

Examiner

Andrea D Small

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-20,31-38 and 41-51 is/are rejected.
- 7) ☒ Claim(s) 6 and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are parts 1-2, 4-20, 31-38 and 41-51 and 3, 21-30 and 39-40.

DETAILED ACTION

I. Applicants Response:

(a) Applicants response filed 4/30/2003 has been received and entered as paper no. 9.

(b) Claim 7, 34 and 38 have been amended.

(c) Claims 49-51 have been newly added.

II. Restriction:

Applicant's election with traverse of group II in Paper No. 9 is acknowledged. The traversal is on the ground(s) that:

(a) Oxygen and sulfur "both have the same valence and would be expected to function in a similar manner in compounds of the structure of formula (I)." Hence, group I and II should be examined together. Examiner agrees with Applicant and groups I and II are examined together to the extent where the Z moiety in the compound of formula (I) is oxygen or sulfur.

(b) Group IV should be examined with claims 39 and 40 as claims 39 and 40 are drawn to a process of preparing formula I where Z is NR₆. The examiner agrees with Applicant and has included claims 39 and 40 with group IV.

(c) Groups where Z is =CH and Z is NR₆ should be examined together as they are classified in the same class and subclass.

The examiner respectfully disagrees. The classification is not the sole reason to restrict between inventions in an application where two or more such inventions are present in one application. 35 USC 121 provides the Office with authority to restrict the application to one invention. The criteria established in the guide MPEP 803 is a two-prong test. One is whether

Art Unit: 1626

the groups are independent or distinct and two, a serious burden must be imposed on the examiner in order to restrict.

Compounds of formula I where Z is =CH is patentably distinct from compounds of formula I where Z is NR₆ because these compounds vary in structure and element so much so that a reference that would anticipate one of these moieties would not even render the other obvious. Additionally, a serious burden will be imposed on the office if restriction is not required because there is an electronic database as well as a manual database search that needs to be conducted. These searches are not co-extensive; they involve separate searching strategies and separate search considerations. For these reasons and the reasons of record, the restriction is proper as outlined.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-2, 4-20, 31-38 and 41-51 read on the elected group, which are drawn to, compounds of formula I, where Z is oxygen or sulfur. The remainder of claims 1-2, 4-20, 31-38 and 41-51 and claims 3, 21-30 and 39-40 are withdrawn from consideration as being drawn to non-elected inventions. 37 CFR 1.142(b).

III. Rejections:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention in claims 34, 37, 38 and 50-51 lack patentable utility. These claims recite a method of treating a bacterial infection by administering the compound of claim 1. The claims do not recite any effective amounts, thus these claims read on an amount that would not be

Art Unit: 1626

effective to treat bacterial infections and an amount that would be toxic to the patient, therefore, a question as to the utility of the process comes into question. Amending these claims to insert the phrase "administering an effective amount of..." is suggested to obviate the above rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(a) Claims 1-2, 4-20, 31-38 and 41-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terms "derivatives, analogs, tautomeric forms, polymorphs and solvates" in claims 1, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 47 and 48 are not described in the disclosure. It is unclear what Applicants contemplate as the derivatives, analogs, tautomeric forms, polymorphs and solvates of the instantly claimed compounds. The disclosure is silent as to how to make and how to use these embodiments of the inventions. For example, the description of the invention does not provide for what type of derivatives are instantly contemplated; what positions on the compounds may be derivatized; what reagents and reaction conditions will result in the contemplated derivatives, etc. The same would apply for the analogs. The tautomeric forms that are contemplated are not described; where are the double bonds on the molecule that may be tautomerized, etc. There are several polymorphs of compounds, some which would need specific reagents or solvents to make; other would require

Art Unit: 1626

particular separating mechanisms to isolate, etc. Depending on the reagents used, the solvates could vary extensively; the description does not give any guidance as to the contemplated solvates of the instantly claimed compounds. Hence, the aforementioned terms lack description in the disclosure.

(b) Claims 1-2, 4-20, 31-38 and 41-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for the compounds of claim 1, does not reasonably provide enablement for the "derivatives, analogs, tautomeric forms, polymorphs and solvates", in claims 1, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 47 and 48, of those compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

Art Unit: 1626

In the instant case, Applicants are claiming a "derivatives, analogs, tautomeric forms, polymorphs and solvates" of the compound of claim 1. The nature of the chemical arts is that there is very little predictability concerning any "derivatives, analogs, tautomeric forms, polymorphs and solvates" of compounds in how they are made and how they are used. For example, there would be very little predictability in the art for one of ordinary skill to prepare an analog of a compound. First, one would have to determine what the structurally similar compound would look like; second, one would have to determine which moieties on the compound result in the desired activity; third, one would have to speculate how to prepare that analog so that the particular moiety would be replicated without disrupting the desired activity, all of which required undue experimentation. The instant specification fails to provide any guidance or any working examples for the contemplated derivatives, analogs, tautomeric forms, polymorphs and solvates that are specifically recited in the instant claims. The breadth of the claims extends to cover those structural derivatives, analogs, tautomeric forms, polymorphs and solvates, which the Applicants have not provided a mechanism for ascertaining the structure, method of making or method of using. In order to practice the invention to the scope of that claimed, one of ordinary skill in the art would require undue experimentation to first prepare the contemplated derivatives, analogs, tautomeric forms, polymorphs and solvates of the compounds and then determine which of those compounds would have the desired activity. This level of unpredictability and level of experimentation required establishes the level of skill in the art would prevent one of ordinary skill to practice the invention commensurate with the scope of the claims without undue experimentation. Thus, the terms "derivatives, analogs, tautomeric forms,

Art Unit: 1626

polymorphs and solvates” of compound of claim 1 are not enabled. Amending the claims to delete said terms would obviate the above rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Braun, et al.

The instant claims relate to compounds of formula I. Braun, et al teach compounds that anticipate the instantly claimed genus where X is oxygen; R1 is OR4, where R4 is H; R2 and R3 are each hydrogen; Y1 is oxygen; and Y2 and Y3 are hydrogen, while the other is hydroxy alkyl. See RN#: 69974-34-1 in abstract provided.

(b) Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Sorokin, et al

The instant claims relate to compounds of formula I. Sorokin, et al teach compounds that anticipate the instantly claimed genus where X is oxygen; R1 is OR4, where R4 is H; one of R2 and R3 is alkyl while the other is hydrogen; Y1 is oxygen; and Y2 and Y3 are hydrogen, while the other is hydroxy alkyl. See RN#: 79473-16-8 in abstract provided.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1626

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braun, et al. OR Sorokin, et al. In view of Werner, et al.

The instant claims relate to compounds of formula I.

Determination of the scope and content of the prior art (MPEP §2141.01)

Braun, et al teach compounds that anticipate the instantly claimed genus where X is oxygen; R1 is OR4, where R4 is H; R2 and R3 are each hydrogen; Y1 is oxygen; and Y2 and Y3 are hydrogen, while the other is hydroxy alkyl. See RN#: 69974-34-1 in abstract provided.

Art Unit: 1626

Sorokin, et al teach compounds that anticipate the instantly claimed genus where X is oxygen; R1 is OR4, where R4 is H; one of R2 and R3 is alkyl while the other is hydrogen; Y1 is oxygen; and Y2 and Y3 are hydrogen, while the other is hydroxy alkyl. See RN#: 79473-16-8 in abstract provided.

Werner, et al teaches 2-oxazolidinone compounds are useful bactericides.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art and the instant claims is that the prior art does not teach the instant claims where Z is sulfur.

Finding of prima facie obviousness---rationale and motivation (MPEP §2142-2413)

However, it would have been prima facie obvious to one of ordinary skill in the art to make additional compounds useful as bactericides structurally similar to those disclosed in Braun, et al or Sorokin, et al, where Z is sulfur, because as Applicants acknowledged in paper no. 9, page 2, lines 5-10, oxygen and sulfur “both have the same valence and would be expected to function in a similar manner in compounds of the structure of formula I”.

IV. Objections:

(a) Claims 6 and 49 are objected to as being in an improper Markush format. It is suggested that Applicant insert an “or” between Zn and Mn in claim 7 or an “,” instead of “;” between Mn and salts.

(b) Claims 1-2, 4-20, 31-38 and 41-51 are objected as containing non-elected subject matter. 37 CFR 1.142(b).

(c) Claims 3, 21-30 and 39-40 are objected to as being drawn to non-elected inventions. 37 CFR 1.142(b).

Art Unit: 1626

V. Contacts:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrea D. Small, whose telephone number is (703) 305-0811. The examiner can normally be reached on Monday-Thursday from 8:30 AM - 7:00 PM.

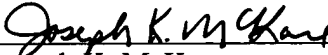
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Joseph.McKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1234

Andrea D. Small, Esq.
May 30, 2003



Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626
Technology Center 1